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October 29, 2019

The Honorable Patrick J. Schiltz
United States District Court
14E U.S. Courthouse
300 South Fourth Street
Minneapolis, MN 55415

Re: *Lawrence Maxcy, individually and on behalf of those similarly situated v. Paul Schnell, et al. (Civil No. 15-2210) (PJS/BRT)*

Dear Judge Schiltz:

Attached please find the Minnesota Department of Corrections' Report for the First Quarter of Fiscal Year 2020 in the above-entitled matter. This letter and report are filed pursuant to the Order Approving Class Action Settlement. (Doc. 339.)

Sincerely,

s/ Kathryn A. Fodness
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Attorney for Defendants Paul Schnell, James Amsterdam, M.D.,¹ and Nanette Larson, in their official capacities only

¹ The case caption reflects Dr. David A. Paulson has been sued in his official capacity as Medical Director of the Minnesota Department of Corrections. Dr. James Amsterdam is now the Medical Director of the Minnesota Department of Corrections. Pursuant to Federal Rule of Civil (Footnote Continued on Next Page)

Enclosure

cc: Katie Crosby Lehmann, Esq. (with enclosure by email and U.S. Mail)
Esther Agbaje, Esq. (with enclosure by email and U.S. Mail)

(Footnote Continued from Previous Page)

Procedure 25(d), Dr. Amsterdam should be substituted for Dr. Paulson for purposes of Plaintiff's official capacity claim.

Re: Report pursuant to Settlement Agreement (Doc. 327-1) and approved by the Court on June 24, 2019 (Doc. 339) – First Quarter of Fiscal Year 2020

The Fiscal Year 2020 (FY 2020) runs from July 1, 2019, through June 30, 2020. The First Quarter of Fiscal Year 2020 ran from July 1, 2019, through September 30, 2019. This Report is submitted pursuant to the Settlement Agreement approved by the Court on June 24, 2019 (Doc. 327-1, 339), and was compiled based on data maintained by the Minnesota Department of Corrections (DOC). Attached hereto is a copy of the Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection (the Guidelines) currently in effect. The Guidelines were implemented beginning June 24, 2019, and were in effect throughout the first quarter of Fiscal Year 2020.

Total number of prisoners ¹ tested for Hepatitis C in the First Quarter of FY 2020	1,486				
Total number of prisoners diagnosed with a positive PCR test in the First Quarter of FY 2020	56				
Total number of prisoners with Hepatitis C who received treatment with Direct Acting Antivirals (DAAs) in the First Quarter of FY 2020 by fibrosis level	F0	F1	F2	F3	F4
	88	3	4	2	2
Total number of prisoners with Hepatitis C who did not receive treatment with DAAs in the First Quarter of FY 2020 by fibrosis level, all who were deferred per the Guidelines	F0	F1	F2	F3	F4
	211	3	5	0	0
Total number of prisoners diagnosed with Hepatitis C who have refused elastography	7				
Total number of prisoners diagnosed with Hepatitis C who are pending the completion of elastography	11				
Total number of prisoners with Hepatitis C receiving DAAs at the end of the First Quarter of FY 2020	75				

¹ The term “prisoners” has the meaning ascribed to it on page 4 of the Settlement Agreement. (Doc. 327-1.)

All prisoners with Hepatitis C who met the Guidelines were treated with DAAs during the First Quarter of Fiscal Year 2020. As of October 1, 2019, a total of 14 prisoners were undergoing a treatment workup.

Dated: 10/24/2019



Christopher Sigstad
Research Analysis Specialist
Minnesota Department of Corrections Health Services
Unit

**Guidelines for Evaluation and Management
of Chronic Hepatitis C (HCV) Infection
06/24/2019**

The goal of the Department is to reduce all-cause mortality and liver related health consequences, including end-stage liver disease and hepatocellular carcinoma, by achievement of virologic cure as evidenced by sustained virologic response (SVR). Priority for antiviral treatment is based on the degree of liver fibrosis and the existence of co-morbidities associated with increased risk of fibrosis progression.

The purpose of these guidelines is to provide direction to health services staff when:

- Screening and testing offenders to determine whether they have a chronic hepatitis C virus (HCV) infection;
- Determining the stage of liver fibrosis in offenders with chronic hepatitis C infection
- Identifying risk factors that are associated progression of fibrosis in those with chronic HCV
- Evaluating HCV infected offenders for treatment with antiviral agents;
- Counseling offenders with chronic HCV; and
- Monitoring the condition of HCV infected offenders before, during and after antiviral treatment.

These guidelines will be updated periodically in accordance with treatment recommendations by nationally recognized authorities, such as the American Association for the Study of Liver Disease (AASLD)/Infectious Disease Society of America (IDSA), the Federal Bureau of Prisons, and other recognized authorities as new treatment strategies and medications are developed.

Background

Hepatitis C is a viral infection most often transmitted by exposure to human blood or body fluids. The most common mode of transmission is through the use of contaminated needles associated with intravenous drug use. Others modes of transmission include sexual, nasal inhalation of drugs, tattooing using unsterile techniques, and getting contaminated blood or body fluids into open wounds or onto mucous membranes. HCV is not transmitted by casual contact such as touching, sharing household items, or by food.

Acute HCV infection is seldom diagnosed because it usually causes few symptoms, therefore the person does not seek medical evaluation. About 25% of acute cases spontaneously resolve without anti-viral treatment. The remainder of cases develop chronic HCV infection. Chronic HCV infection typically is asymptomatic for many years and can only be diagnosed by blood

testing. Over time chronic HCV infection can cause permanent and potentially life threatening liver disease. Progression to advanced liver disease is a slow process generally taking 20-25 years. The most important factor in causing liver disease progression is excessive alcohol consumption. Other factors for progression include co-infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV) infection, and other liver related conditions. Chronic hepatitis C can negatively impact or worsen certain other medical conditions. Advanced liver fibrosis is a risk factor for liver cancer.

Goals

The objectives of the Department in establishing these HCV guidelines are as follows:

- To identify offenders infected with HCV;
- To provide appropriate education and counseling to offenders on the nature of the disease and its transmission and how to prevent disease progression;
- To identify those offenders that are most likely to experience life altering or threatening complications of HCV so they can receive antiviral treatment;
- To provide appropriate antiviral treatment to these offenders; and
- To prevent spread of HCV through education and treatment.

Achievement of these goals and objectives begins at intake with a series of HCV specific testing and, for offenders with chronic HCV, continues throughout their time in MN DOC custody.

1. Intake screening and testing for HCV Infection

At intake, DOC nursing staff will:

- a. Explain risk factors for HCV infection and methods of transmission of HCV to offenders;
- b. Inform the offender that the DOC tests all offenders for hepatitis C at intake unless the offender declines (opts out) of the test;
- c. Order the HCV blood test unless the offender declines the test;
- d. Provide education and written information on HCV transmission, the natural history of HCV infection, potential health implications of HCV infection, what HCV testing involves, and how chronic HCV infection is managed and treated in the MN DOC;
- e. Explain procedures for following up on HCV tests; and
- f. Inform offenders who decline the intake test, that they may request the HCV test at a future time.

2. Blood Testing for HCV

- a. Blood tests for HCV include a screening blood test for the HCV antibody and, if that test is positive, a confirmatory test for HCV virus to determine whether the offender has active infection. (The confirmatory test is done as a reflex test.)

- b. Offenders who decline intake testing may request HCV blood testing at a later date. Repeat screening tests must be ordered by a practitioner.

3. Evaluating HCV Infected Offenders

Nursing staff will schedule an initial practitioner visit to follow-up on all positive HCV PCR tests (tests indicating active hepatitis C infection). Initial and follow-up care for offenders with HCV infection is not subject to the offender co-payment.

a. Initial Evaluation

Practitioners will conduct an initial evaluation that includes:

- 1) A targeted history and physical exam;
 - 2) Laboratory tests including: (these tests may be done prior to the initial visit)
 - Complete blood count (CBC)
 - Complete metabolic profile (CMP)
 - International normalized ratio (INR)
 - HIV antigen/antibody test
 - Hepatitis B surface antigen, surface antibody and hepatitis B core antibody
 - Hepatitis A antibody
 - Additional tests that the practitioner determines are indicated;
 - HCV genotype test may be delayed until antiviral treatment is planned;
 - 3) Order immunization for hepatitis A and B if indicated;
 - 4) Order pneumococcal vaccine, if there is evidence of cirrhosis;
 - 5) Explanation of the process for periodic evaluation and criteria for determining treatment eligibility;
 - 6) Providing the offender with recommendation for frequency of follow-up;
 - 7) Staging elastography and limited abdominal ultrasound will be done on offenders with HCV chronic infection. (This may be done after the initial evaluation.); or, other medically appropriate staging test such as liver biopsy, blood tests, physical examination, magnetic resonance imaging, or computerized tomography;
 - 8) When cirrhosis is known, referral for:
 - Endoscopic screening for esophageal varicosities
 - Liver ultrasound (this is done routinely in conjunction with elastography)
- b. Periodic Evaluation of Chronic Infection
- Offenders with chronic HCV will be evaluated periodically to monitor for the progression of liver disease and other complications.

- 1) Offenders are responsible for requesting periodic evaluations of their condition. Generally, re-evaluation should be done every 6 months or more often if the practitioner recommends this.
- 2) Practitioners at the facilities will conduct the periodic evaluations, which will generally consist of:
 - a) An interim targeted history and physical exam;
 - b) Laboratory testing, CBC, CMP, and INR;
 - c) Ultrasound screening for liver cancer every 6 months for offenders with stages 3 and 4 fibrosis
(This screening is indicated for both treated and untreated cases.); and
 - c) Other testing as clinically indicated including repeat liver elastography (see 8 below).
- c. Case Reports
Practitioners and/or facility staff will:
 - 1) Complete a Hepatitis C Case Report after the initial evaluation;
 - 2) Complete a new case report after each periodic evaluation; and
 - 3) Case report documentation;
 - a) File the case report in the offender's medical record; and
 - b) Send a copy of each case report and to the DOC medical director or designee.

4. Determining the stage of liver fibrosis

- a. Offenders with chronic HCV infection will be offered testing to determine their stage of liver fibrosis (Metavir stage 0-4).
- b. The standard staging test is ultrasound based shear wave elastography and limited abdominal ultrasound. In combination, these two tests determine the stage of fibrosis and can detect other liver conditions including signs of decompensated cirrhosis, fatty liver disease, liver masses and infection. These 2 tests are non-invasive and done as a combined procedure.
- c. Other tests may be used to determine liver fibrosis stage such as liver biopsy, blood tests, physical examination, magnetic resonance imaging or computerized tomography.

5. Anti-viral Treatment

All offenders with chronic HCV infection are eligible for consideration of antiviral treatment. The DOC Medical Director or designee may authorize patient-specific antiviral treatment for offenders who have chronic HCV infection.

(Note: Acute HCV infection is seldom diagnosed because the symptoms are generally mild and non-specific. Anti-viral treatment is not indicated for acute cases, since a substantial proportion spontaneously resolve.)

Eligibility Criteria: In the absence of an exclusion or deferral condition(s) noted below, the DOC will provide HCV antiviral treatment to offenders who have:

- Liver Fibrosis stages 1, 2, 3 and 4 (based on elastography, liver biopsy or other clinical indicators).
 - HCV and concurrent chronic hepatitis B or HIV infection;
 - Certain other co-morbid conditions or extra-hepatic manifestations of chronic HCV infection such as cryoglobulinemia;
 - Sufficient incarceration time to complete the course of treatment (up to 24 weeks);
 - Been admitted to DOC receiving uninterrupted and documented HCV anti-viral treatment;
 - Had a liver transplant;
 - Have hepatocellular carcinoma;
 - Certain other malignancies;
 - Co-morbid liver disease [e.g. autoimmune hepatitis, hemochromatosis or non-alcoholic steatohepatitis (NASH)];
 - Renal insufficiency with GFR less than or equal to 59mL/min per 1.73 square meters;
 - Diabetes mellitus.
 - Fibrosis Stage F0 (based on elastography, liver biopsy or other clinical indicators) provided that the offender has been in a Minnesota Correctional facility for a continuous period of 16 months, and has 24 weeks or more remaining in prison.
- c. Exclusion or deferral from treatment. The following conditions or situations are indications for deferral of anti-viral treatment:
- Contraindications based on drug interactions or concurrent medical conditions;
 - Planned medical treatment, such as surgery, that may interfere with the medication or continuity of HCV treatment with DAAs;
 - Life expectancy of less than 18 months;
 - Inability or unwillingness to adhere or cooperate with the treatment or clinical monitoring;
 - Current pregnancy;
 - Evidence of active IV drug use.

6. Treatment regimens

- a. Only medications approved by the Food and Drug Administration (FDA) will be used for HCV treatment

- b. Anti-viral treatment will be consistent with current treatment recommendations established by nationally recognized authorities, such as the American Association for the Study of Liver Disease (AASLD), FBOP, FDA, and/or others.
- c. Patient specific factors in medication selection include:
 - Virus genotype;
 - HCV viral load;
 - Fibrosis stage;
 - Co-existing medical conditions;
 - Medication interactions (real or possible);
 - Prior HCV treatment history;
 - Known or suspected viral medication resistance;
 - Adherence with previous medical treatment and/or monitoring; and
 - Cost effectiveness.
- c. HCV anti-viral treatment will be administered as directly observed therapy by nursing staff.

7. Monitoring During and After Anti-viral Treatment

Practitioners and nurses at each facility will monitor treatment to identify medication side effects and toxicity and to ensure that offenders who are receiving anti-viral treatment are adhering to their treatment regimens and monitoring, and to determine the effectiveness of the treatment.

- a. Practitioners will obtain lab tests prior to and during treatment weeks, as established by the lab monitoring guidelines.
- b. Practitioners and/or facility staff will report to the DOC Medical Director all information regarding the effectiveness and/or safety of HCV antiviral treatment, including such examples as:
 - 1) The offender does not comply with the treatment regimen, clinical monitoring or lab testing;
 - 2) The offender has a significant adverse or allergic reaction to a medication that cannot be managed medically;
 - 3) Laboratory tests reveal evidence of treatment failure based on continued presence of HCV virus in the blood;
 - 4) The offender is experiencing an adverse effect of treatment based on clinical findings or laboratory testing, or
 - 5) There is evidence that the offender is using illicit drugs or alcohol use during treatment.

8. Monitoring when anti-viral treatment is deferred

- a. Offenders with untreated chronic HCV will be monitored on an ongoing basis for progression of liver disease or development of complications.
- b. Offenders with an APRI score greater than 2.0 or a FIB-4 score greater than 3.25 at a follow-up evaluation will be offered an ultrasound elastography for restaging. Should the elastography study show that the offender has Stage 1,2,3,or 4 fibrosis, the offender will be treated with antivirals, provided the offender has at least 24 weeks remaining on his or her current term of imprisonment and not of the exclusions (number 7 above).

March 25, 2019